

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

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Atty. Doc.: Rijk-15(P52075US00)

Serial No.: 10/009,579 Filed: March 22, 2002

Group Art Unit: 1636 Confirmation No.: 1723

Examiner: Celine X. Qian

Title: NON-SQUAMOUS EPITHELIUM-SPECIFIC TRANSCRIPTION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SIR:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Office Action dated February 25, 2004 (Paper Number 0204) which imposed a restriction requirement in the above-captioned patent application.

The requirement for restriction by the Examiner is traversed as follows:

Applicants contend that the argument of the Examiner that the special technical feature of Group I is "a tissue specific promoter or a fragment of that promoter that selectively expresses carcinoma cells". In fact, what the Examiner intended to state is that the special technical

feature of Group I is a fragment of that promoter that is selectively expressed in carcinoma cells.

The Examiner further urges that the technical feature in issue is known from the disclosure of Baptist et al relating to the tumor specific Hex II promoter and therefore Applicants' invention cannot be linked as a whole to form a single inventive concept.

Applicants vigorously contend that the technical feature identified by them is not disclosed in the prior The tumor specific promoter of Baptist et al is not the same as a carcinoma selective promoter as disclosed in the instant invention. As stated on page 2, lines 254-30 of the description, the HEX II promoter of Baptist is not restricted to or selective for carcinomas but extends to be expressed in all tumor cells and beyond. The technical feature of claim 1 as defined by the Examiner is therefor novel and inventive over the prior art, thereby negating the validity of the restriction requirement. Furthermore, the novelty of the promoter is irrelevant for distinguishing the noted groups. It is therefore logical that the inventions of Groups I and III be considered as one invention. Accordingly it is urged that the requirement for restriction be withdrawn.

Applicants further note that instant application complies with the requirement of unity of invention during the PCT stage by the International Preliminary Examining Authority and it is urged that the opinion of the IPEA be followed by the Examiner.

In order to comply with the requirements of 35 U.S.C. 121 and 372, Applicants provisionally elect the claims of Group I which includes claims 1-10 drawn to a nucleic acid comprising a tissue specific promoter or a fragment of that promoter that selectively expresses carcinoma cells, a vector comprising said nucleic acid and a host cell comprising said nucleic acid.

In conclusion, it is urged that the requirement for restriction be withdrawn and that all claims in the application be considered a component of a singular invention.

Respectfully submitted,

May <u>28</u>, 2004

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